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| | | | | Application Number | 10/681,018 |
| | | | | Filing Date | October 8, 2003 |
| | | | | First Named Inventor | Joan M. Fallon |
| | | | | Art Unit | 1649 |
| | | | | Examiner Name | Kimberly Ballard |
| Sheet | 1 | of | 7 | Attorney Docket Number | 41012-701.301 |

## U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No.[1] | Document Number<br>Number-Kind Code[2] *(if known)* | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|
| | 1. | 13/002,136 | Appln date 12/30/10 | Fallon | |
| | 2. | US 2002/0037284 A1 | 03/01/2002 | Fallon | |
| | 3. | US 2002/0081628 A1 | 06/27/2002 | Fallon | |
| | 4. | US 2002/0090653 A1 | 07/11/2002 | Fallon | |
| | 5. | US 2004/0076590 A1 | 04/22/2004 | Wilkins | |
| | 6. | US 2004/0101562 A1 | 05/27/2004 | Maio | |
| | 7. | US 2004/0121002 A1 | 06/24/2004 | Lee et al. | |
| | 8. | US 2004/0209790 A1 | 10/24/2004 | Sava et al. | |
| | 9. | US 2005/0187130 A1 | 08/25/2005 | Booker et al. | |
| | 10. | US 2006/0105379 A1 | 05/18/2006 | Wu et al. | |
| | 11. | US 2006/0182728 A1 | 08/17/2006 | Fallon | |
| | 12. | US 2006/0183180 A1 | 08/17/2006 | Fallon | |
| | 13. | US 2006/0198838 A1 | 09/07/2006 | Fallon | |
| | 14. | US 2006/0259995 A1 | 11/16/2006 | Cayouette et al. | |
| | 15. | US 2007/0116695 A1 | 05/24/2007 | Fallon | |
| | 16. | US 2008/0058282 A1 | 03/06/2008 | Fallon | |
| | 17. | US 2008/0152637 A1 | 06/26/2008 | Fallon | |
| | 18. | US 2008/0161265 A1 | 07/03/2008 | Fallon et al. | |
| | 19. | US 2008/0166334 A1 | 07/10/2008 | Fallon | |
| | 20. | US 2008/0219966 A1 | 09/11/2008 | Fallon | |
| | 21. | US 2008/0254009 A1 | 10/01/2008 | Finegold | |
| | 22. | US 2008/0279839 A1 | 11/13/2008 | Schuler et al. | |
| | 23. | US 2008/0317731 A1 | 12/25/2008 | Gramatikova et al. | |
| | 24. | US 2009/0130081 A1 | 05/21/2009 | Fallon | |
| | 25. | US 2009/0197289 A1 | 08/06/2009 | Fallon | |
| | 26. | US 2009/0232789 A1 | 09/17/2009 | Fallon | |
| | 27. | US 2009/0263372 A1 | 10/22/2009 | Fallon | |
| | 28. | US 2009/0285790 A1 | 11/19/2009 | Fallon | |

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|---|---|---|---|---|---|
| | 29. | US 2009/0286270 A1 | 11/19/2009 | Fallon | |
| | 30. | US 2009/0324572 A1 | 12/31/2009 | Fallon | |
| | 31. | US 2009/0324730 A1 | 12/31/2009 | Fallon | |
| | 32. | US 2010/0092447 A1 | 04/15/2010 | Fallon | |
| | 33. | US 2010/0169409 A1 | 07/01/2010 | Fallon et al. | |
| | 34. | US 2010/0233218 A1 | 09/16/2010 | Fallon | |
| | 35. | US 2010/0260857 A1 | 10/14/2010 | Fallon et al. | |
| | 36. | US 3,002,883 | 10/03/1961 | Butt et al. | |
| | 37. | US 3,357,894 | 12/12/1967 | Jose et al. | |
| | 38. | US 3,940,478 | 02/24/1976 | Kurtz | |
| | 39. | US 4,145,410 | 03/20/1979 | Sears | |
| | 40. | US 4,241,046 | 12/23/1980 | Papahadjopoulos et al. | |
| | 41. | US 5,324,514 | 06/28/1994 | Sipos | |
| | 42. | US 5,858,758 | 01/12/1999 | Hillman et al. | |
| | 43. | US 6,011,001 | 01/04/2000 | Navia et al. | |
| | 44. | US 6,187,309 | 02/01/2001 | McMichael et al. | |
| | 45. | US 6,280,726 | 08/01/2801 | Weinrauch et al. | |
| | 46. | US 6,309,669 | 10/30/2001 | Setterstrom et al. | |
| | 47. | US 6,534,259 | 03/01/2003 | Wakefield | |
| | 48. | US 6,727,073 | 04/01/2004 | Moore et al. | |
| | 49. | US 6,743,447 | 06/01/2004 | Labergerie et al. | |
| | 50. | US 6,797,291 | 09/28/2004 | Richardson | |
| | 51. | US 6,835,397 | 12/28/2004 | Lee et al. | |
| | 52. | US 6,852,487 | 02/01/2005 | Barany et al. | |
| | 53. | US 7,129,053 | 10/01/2006 | Reiter et al. | |

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|---|---|---|---|---|---|---|
| | 54. | EP 0451484 A1 | 10/16/1991 | Brzeczko et al. | | |
| | 55. | EP 0564739 A3 | 04/26/1995 | Gilon et al. | | |
| | 56. | WO 01/27612 A2 | 04/19/2001 | Reiter et al. | | |
| | 57. | WO 01/27612 A3 | 10/11/2001 | Reiter et al. | | |
| | 58. | WO 2002/014537 A2 | 02/21/2002 | Fallon | | |
| | 59. | WO 2002/014537 A3 | 05/10/2002 | Fallon | | |
| | 60. | WO 2009/114757 A2 | 09/17/2009 | Fallon | | |
| | 61. | WO 2010/002972 A1 | 01/07/2010 | Fallon | | |
| | 62. | WO 2010/080830 A1 | 07/15/2010 | Fallon et al. | | |
| | 63. | WO 2010/080835 A1 | 07/15/2010 | Fallon et al. | | |

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| **NON PATENT LITERATURE DOCUMENTS** | | | |
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| | 64. | Amendment and Response dated 4/7/2010 in Reply to Restriction Requirement dated 10/7/09 for US Application 12/283,090. | |
| | 65. | Amendment and Response dated 6/30/10 to Restriction Requirement dated 1/13/10 for US Application 12/487,868. | |
| | 66. | Amendment dated 3/24/10 in Reply to Final Office Action dated 7/2/10 for US Application 12/046,252. | |
| | 67. | BRUDNAK et al. Enzyme-based therapy for autism spectrum disorders -- is it worth another look? Med Hypoth. 2002; 58:422-428. | |
| | 68. | CRUSE et al. Illustrated dictionary of immunology. CRC Press, New York. 1995. | |
| | 69. | Final Office Action dated 11/9/10 for US Application 09/990,909. | |
| | 70. | Final Office Action dated 2/14/11 for US Application 12/049,613. | |
| | 71. | Final Office Action dated 5/11/10 for US Application 11/555,697 | |
| | 72. | Final Office Action dated 7/2/10 for US Application 12/046,252. | |
| | 73. | GARCIA et al. Detection of giardia lamblia, entamoeba histolytica/entamoeba dispar, and cryptosporidium parvum antigens in human fecal specimens using the triage parasite panel enzyme immunoassay. Am Soc for Microbiology. 2000; 38(9):3337-3340. | |
| | 74. | HENDREN et al. Mechanistic biomarkers for autism treatment. Medical Hypotheses. 2009; 73:950-954. | |
| | 75. | HORVATH et al. Improved social and language skills after secretin administration in patients with autistic spectrum disorders. Journal of the Association for Academic Minority Physicians. January 1998; 9(1):9-15. Duplicate ref. Do not print. KAB | |
| | 76. | International search report and written opinion dated 3/2/10 for PCT/US2010/020253 | |

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| | 77. | International search report and written opinion dated 3/5/10 for PCT/US2010/020259 | |
| | 78. | International search report and written opinion dated 2/15/11 for PCT/US2010/053484 | |
| | 79. | International search report and written opinion dated 1/18/11 for PCT/US2010/057341 | |
| | 80. | International search report and written opinion dated 6/9/10 for PCT/US2010/030895 | |
| | 81. | KASPAR et al. New photometric assay for chymotrypsin in stool. Clinical Chemistry. 1984; 30(11):1753-1757. | |
| | 82. | LIEBERMAN. Pharmaceutical Dosage Forms. Vol. 2: Disperse Systems. New York Marcel Dekker, Inc. 1996; 243-258. | |
| | 83. | LIPASE 30, Technical Data sheet, 1 page, Scientific Protein Laboratories LLC 6/13/05 | |
| | 84. | MUNASINGHE et al. Digestive enzyme supplementation for autism spectrum disorders: a double-blind randomized controlled trial. J Autism Dev Disord. Mar 5 1010; Epub ahead of print. | |
| | 85. | NEVO et al. Acute immune polyneuropathies: correlations of serum antibodies to campylobacter jejuni and helicobacter pylori with anti-gm antibodies and clinical patterns of disease. J of Inf diseases. 1997; 175(S2):S154-6. | |
| | 86. | Notice of Non-Compliant Amendment dated 4/27/10 for US Application 12/283,090. | |
| | 87. | Office Action dated 1/21/11 for US Application 12/386,051. | |
| | 88. | Office Action dated 1/29/02 for US Application 09/707,395. | |
| | 89. | Office Action dated 10/1/01 for US Application 09/466,559. | |
| | 90. | Office Action dated 10/5/10 for US Application 12/046,402. | |
| | 91. | Office Action dated 11/15/10 for US Application 12/238,415. | |
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| | 95. | Office Action dated 5/22/02 for US Application 09/466,559. | |
| | 96. | Office Action dated 7/22/10 for US Application 12/049,613. | |
| | 97. | Office Action dated 7/30/02 for US Application 09/707,395. | |
| | 98. | Office Action dated 7/6/10 for US Application 11/533,818. | |
| | 99. | Office Action dated 8/13/02 for US Application 09/929,592. | |
| | 100. | Office Action dated 8/20/10 for US Application 12/283,090. | |
| | 101. | Office Action dated 8/25/10 for US Application 12/487,868. | |
| | 102. | Pancreatic Enzyme Concentrate (PEC) Undiluted, Technical Data Sheet. 1 page, Scientific Protein Laboratories LLC 6/13/05 | |
| | 103. | Pancreatin 4X USP, Technical Data Sheet, 1 page, Scientific Protein laboratories LLC 6/13/05 | |
| | 104. | PERMAN et al. Role of ph in production of hydrogen from carbohydrates by colonic bacterial flora. J Clin Invest. 1981; 24(4):684-685. | |
| | 105. | PETERS et al. Prevalence of enteric parasites in homosexual patients attending an outpatient clinic. J of Clin Micro. 1986; 24(4):684-685. | |
| | 106. | REMTULLA et al. Stool chymotrypsin activity measured by a spectrophotometric procedure to identify pancreat disease in infants. Clinical Biochemistry. Dec 1986; 19:341-342. | |
| | 107. | Response dated 4/29/10 to Notice of Non-Compliant Amendment dated 4/27/10 for US Application 12/283,090. | |
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| | 109. | Restriction Requirement dated 10/7/09 for US Application 12/283,090. | |
| | 110. | SANDLER et al. Short term benefit from oral vancomycin treatment of regressive-onset autism. J of Child Neuro. 2000; 15(7):42-435. | |
| | 111. | SKEELS et al. Crytosporidium infection in Oregon public health clinic patients 1985-88: the value of statewide laboratory surveillance. AJPH. 1990; 80(3):305-308. | |
| | 112. | Supplemental Amendment and Response dated 6/8/10 to Restriction Requirement dated 10/7/09 for US Application 12/283,090. | |
| | 113. | USP (32)-NF(27) 2009, Pancreatin, V.3, pp.3194-3195. | |
| | 114. | WENDER et al. Prevalence of attention deficit disorder, residual type, and other psychiatric disorders in patients with irritable colon syndrome. Am J Psychiatry. 1983; 140(12):1579-82 Abstract only. | |
| | 115. | WOHLMAN et al. Enhancement of drug activity by chymotrypsin, penicillin penetration into granulomatous sesions and inflammatory fluids. Cellular and Molecular Life Sciences. 1969; 25(9):953-954. | |
| | 116. | ZHANG et al. Lactulose-mannitol intestinal permeability test in children with diarrhea caused by rotavirus abd cryptosporidium. J of Pediatric Gastro & Nutrition. 2000; 31(1):16-21. | |

| Examiner Signature | /Kimberly Ballard/ | Date Considered | 04/14/2011 |
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